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(54) A cleansing-agent composition and its use.

(57) The invention relates to a cleansing-agent composition containing boric acid, and its use for cleansing e.g. the skin, clothing and fixtures from substances which form water-soluble complexes with boric acid, and specifically for removing from the skin the surplus of dithranol in the treatment of psoriasis.

The cleansing-agent composition is characterized in that it comprises the following constituents (based on the weight of the composition):

- a) boric acid, 1 - 3 %;
- (b) anionic detergent, 0.5 - 20 %, preferably 10 - 15 %;
- (c) fatty alcohol, 5 - 30 %, preferably 20 - 25 %; and
- (d) fatty vehicle comprising ethoxylated glycerides of saturated fatty acids and optionally glycerides of unsaturated and/or saturated fatty acids, 30- 75 %.

EP 0 355 368 A2

A cleansing-agent composition and its use

The invention relates to a cleansing-agent composition containing boric acid, and its use for cleansing e.g. the skin, clothing and fixtures from substances which form water-soluble complexes with boric acid, and specifically for removing from the skin the surplus of dithranol in the treatment of psoriasis.

One of the preparations most commonly used for the treatment of psoriasis is dithranol. Dithranol does not cause permanent or severe side effects, as do cortisone derivatives, but its use has been limited by skin irritation caused by its oxidation via radicals, as well as by the coloration of the skin and e.g. clothing. In recent years it has been possible to reduce these drawbacks by using dithranol in stick form, as disclosed in Patent FI 66533, in which case the treatment can be focussed mainly on plaques of eczema, or as so-called minute therapy, short-contact therapy, in which the excess of dithranol is removed from the skin 10-20 minutes after the application (Runne et al., *Hautarzt* 1985:36 40-46). The removal of the dithranol surplus requires absorption of the therapeutic ointment by a soft paper towel, for example by patting the treated areas with a paper towel, and additionally by washing with acidic or neutral washing liquids which do not accelerate the oxidation of dithranol into colored compounds. In order to avoid the staining of the skin, clothing and bathroom fixtures, as well as the irritation of the skin, in short-contact dithranol therapy, it must be possible to remove the surplus dithranol rapidly and as completely as possible. The removal of dithranol by mere washing is difficult, since dithranol and its dark oxidation products are practically water-insoluble and adhere to the skin as well as to fibers and bathroom fixtures. In addition, dithranol preparations are based on water-immiscible fatty vehicles, such as petrolatum and paraffins, 1) since dithranol is better soluble in petrolatum and paraffins than in other ointment bases, 2) since dithranol is more stable in them than in water-containing ointment bases, and 3) since dithranol is taken up by the skin better from then than from water-containing or hydrophilic ointment bases.

So far, boric acid has been used in various skin cleansers mainly as a buffer or as a desinfectant, as described in FR-A-2480120. Alkali borates and borax have been used in skin cleansing preparations as scouring agents in order to increase the cleansing effect (FR 2172803 and DE 2033016) or in order to provide a protective ointment layer on the skin (FR 2231397). However, the ability of boric acid to form water-soluble complexes (chelates) with certain water-insoluble substances, specifically with dihydrodiols which contain cyclic hydrocarbons, has so far not been exploited in skin cleansing agents.

In order to eliminate the above problems encountered in dithranol treatment, a new washing ointment composition has been developed. The constituents of the washing ointment according to the invention facilitate the emulsification of the fatty vehicles of dithranol preparations and the conversion of dithranol into a water-soluble borate chelate, which ensures the rapid and complete removal e.g. from the skin of any dithranol surplus remaining in the horny layer and the surface of the skin. This for its part prevents the coloration of the skin, clothing and bathroom fixtures, and reduces skin irritation. At the same time, the invention renders unnecessary the patting of the skin with paper towels before washing and the use of simple creams after the wash. The invention is also suitable for washing, immediately after staining, any fibers and surfaces stained by dithranol preparations. Furthermore, the invention can also be used for removing from the skin and surfaces, for example in an industrial environment, other substances which form chelates with boric acid.

The constituents of the composition according to the invention constitute an optimal composition for converting dithranol into water-soluble borate chelate in mildly acid or almost neutral conditions. At the same time the anionic detergent and fats present in the ointment facilitate the emulsification of both petrolatum and paraffins and more hydrophilic ointment bases into washable micelles. Borate ions capture into the aqueous phase the dithranol molecules which have ended up on the surface of the micelles because of their hydroxyl groups. In the washing water the water-soluble borate chelates of dithranol remain without breaking down to dithranol at least for the duration of the washing, and the dithranol removed from the skin leaves the washing bowl in a water-soluble form and does not cause coloration of the fixtures.

The borate chelate of dithranol is strongly greenish yellow fluorescent in UV light, and the fluorescence disappears as soon as the dithranol is no longer present in the chelate form (Mustakallio et al., *Psoriasis: Proceedings of the Third International Symposium, Stanford University 1981*, pp. 375-376). This fluorescence phenomenon can be exploited in measuring the rapidness and completeness of the washing off of the dithranol surplus and the stability of the water-soluble dithranol borate chelate in the washing water. When a paraffin-, petrolatum-, or emulsion-based dithranol preparation is used in short-contact therapy and the washing ointment according to the invention is used for the wash in an amount approximately double that of the dithranol preparation, the surplus dithranol can be removed by one post-treatment wash in some twenty seconds, determined by the measurement of fluorescence of the skin and of the washing water and

furthermore proved by the fact that a repeat application of the ointment does not cause fluorescence in fresh washing water.

Owing to the protective and anti-drying fats present in it, the composition according to the invention does not cause drying or additional irritation of the skin even during a month's period of daily treatment. On the other hand, when conventional acidic or neutral cleansing liquids are used in connection with short contact dithranol therapy, it is in general necessary to use some simple cream to reduce the drying and irritation of the skin. The ointment-like properties of the composition according to the invention can, furthermore, be improved by means of conventional constituents used in ointment bases, for example by means of glycerol. The washing ointment according to the invention is also suitable for the washing of textiles and plastics as well as ceramic and enamel surfaces stained by dithranol preparations, if the washing is carried out before the dithranol has oxidized into dark compounds, which is accelerated by alkaline conditions.

The composition according to the invention comprises the following constituents, the concentration limits (in percent by weight) and functioning principles of which are described below:

(1) Boric acid (1 - 3 %)

is an essential constituent of the invention, and together with a water-containing anionic detergent (2) it provides a possibility for the formation of borate ions in almost neutral conditions, in which case the rate of formation and stability of the water-soluble dithranol borate chelate are optimal for the washing purpose.

(2) An anionic detergent (0.5 - 20 %), preferably (10 - 15 %),

for example sodium lauryl ether sulfate (70 %) or any similar sodium salt of sulphated higher primary aliphatic alcohols, together with a fatty alcohol (3) is that constituent of the invention which emulsifies petrolatum and paraffins into micelles and at the same time provides sodium ions for the boric acid, promoting, by buffering, the formation of dithranol borate chelate.

(3) A fatty alcohol (5 - 30 %), preferably (20 - 25 %),

for example cetostearyl alcohol, together with an anionic detergent (2) is that constituent of the invention (emulsifying wax for washable ointments) which emulsifies even petrolatum and paraffins into micelles to be carried away by a washing-water flow.

(4) A fatty vehicle (30 - 75 %),

comprises glycerides of unsaturated and/or saturated fatty acids (for example ricinoleic acid glyceride) and/or glycerides of saturated fatty acids, rendered water-soluble by ethoxylation (e.g. PEG-6 Caprylic/Capric Glyceride). The fatty vehicles protect the skin from irritation, prevent the skin from drying, and accelerate the normalization of its fat content after the wash. They are also more easily emulsifiable than paraffins and petrolatum, the emulsification of which they promote. If the fatty vehicle has a mono-di-glyceride structure, it also has emulsion-stabilizing action. The glyceride of a fatty acid which contains free hydroxyl groups (such as ricinoleic acid) binds dithranol to some extent via hydrogen bridges.

The invention is illustrated by the following examples without, however, restricting this invention:

Example 1

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| Boric acid | 1.0 |
| Sodium lauryl ether sulfate (70 %) | 10.0 |
| Cetostearyl alcohol | 22.0 |
| Ricinoleic acid glyceride (Softigen 701) | 5.0 |
| PEG-6 Caprylic/Capric Glyceride (Softigen 767) | 61.0 |

50 The washing ointment according to Example 1 is suitable for long-term use, since the glyceride of ricinoleic acid renders it gentle for the skin.

Example 2

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| Boric acid | 3.0 |
| Sodium lauryl ether sulfate (70 %) | 15.0 |
| Cetostearyl alcohol | 25.0 |
| PEG-6 Caprylic/Capric Glyceride (Softigen 767) | 57.0 |

The washing ointment according to Example 2 has a stronger washing action and is best suited for removing the surplus dithranol when preparations having a high dithranol content are used.

Example 3

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| Boric acid | 2.0 |
| Sodium lauryl ether sulfate (70 %) | 10.0 |
| Cetostearyl alcohol | 20.0 |
| Ricinoleic acid glyceride (Softigen 701) | 5.0 |
| Glycerol | 5.0 |
| PEG-6 Caprylic/Capric Glyceride (Softigen 767) | 58.0 |

The appearance and convenience in use of the washing ointment according to Example 3 are good.

Claims

1. A cleansing-agent composition, characterized in that it comprises the following constituents (based on the weight of the composition):
 - a) boric acid, 1 - 3 %;
 - (b) anionic detergent, 0.5 - 20 %, preferably 10 - 15 %;
 - (c) fatty alcohol, 5 - 30 %, preferably 20 - 25 %; and
 - (d) fatty vehicle comprising ethoxylated glycerides of saturated fatty acids and optionally glycerides of unsaturated and/or saturated fatty acids, 30 - 75 %.
2. A composition according to claim 1, characterized in that the anionic detergent is a 70 % sodium lauryl ether sulfate.
3. A composition according to one or both of the claims 1-2, characterized in that the fatty alcohol/detergent combination is an emulsifying wax for washable ointments.
4. A composition according to one or more of the claims 1 - 3, characterized in that the fatty alcohol is cetostearyl alcohol.
5. A composition according to one or more of the claims 1 - 4, characterized in that the fatty vehicle comprises an ethoxylated glyceride of natural saturated vegetable fatty acids or PEG-6 Caprylic/Capric Glyceride.
6. Composition according to one or more of the claims 1 - 5, characterized in that the fatty vehicle contains an ester of an unsaturated fatty acid which contains free hydroxyl groups, e.g. ricinoleic acid glyceride, or a fatty acid mono-di-glyceride.
7. The use of compositions according to one or more of the claims 1 - 6 as a cleansing agent in industry for removing substances which form water-soluble complexes with boric acid.
8. The use according to claim 7, characterized in that the substances forming water-soluble complexes with boric acid are dihydrodiols which contain cyclic hydrocarbons.
9. The use according to one or both of the claims 7-8, characterized in that the substance forming water-soluble complexes with boric acid is dithranol, and e.g. a surplus of dithranol is removed from the skin of a psoriatic patient, without staining the skin.
10. The use of compositions according to one or more of the claims 1 - 6, for cleaning fixtures or clothing stained with dithranol.
11. A composition according to one or more of the claims 1 - 6, characterized in that it comprises the following constituents (based on the weight of the composition):

- (a) boric acid, 1 - 3 %;
- (b) sodium lauryl ether sulfate (70 %), 10 - 15 %;
- (c) cetostearyl alcohol, 20 - 25 %; and
- (d) PEG-6 Caprylic:Capric Glyceride, 50 - 65 %.

5 12. A composition according to one or more of the claims 1 - 6, characterized in that it comprises the following constituents (based on the weight of the composition):

- (a) boric acid, 1 - 3 %;
- (b) sodium lauryl ether sulfate (70 %), 10 - 15 %;
- 10 (c) cetostearyl alcohol, 20 - 25 %;
- (d) ricinoleic acid glyceride, 5 - 10 %; and
- (e) PEG-6 Caprylic:Capric Glyceride, 50 - 65 %.

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